

State of Tennessee Department of Children's Services

Administrative Policies and Procedures: 6.1

Subject: **Research Proposals**

> Supersedes: DCS 6.1, 11/01/01 **Local Policy: No**

> > **Local Procedures: No Requires Training: No**

Approved by: **Effective date:** 02/01/00 Nichalfiele

Revised date: 09/01/03

Application

To All Department Of Children's Services Employees, youth, family/children clients, volunteers, all persons requesting research information or data not already in the public domain and all persons requesting and/or participating in the conduct of research activities within the scope of the department.

TCA 37-5-105, TCA 37-5-106, TCA 37-5-107, TCA 37-5-112, TCA Authority:

37-5-113. TCA 37-5-115

Policy

The Department of Children's Services (DCS) supports and cooperatively engages in research activities that expand knowledge of benefit to the children/youth it serves or to the programs it operates. DCS supports and cooperatively engages in research initiatives that contribute to the establishment of future goals and objectives or that contribute to more effective, efficient and economical departmental operation or services delivery. DCS shall adhere to State and Federal Rules and Regulations and DCS Policies and Procedures to ensure protection of confidentiality of clients and participants.

Procedures

A. Scope

1. The Department of Children's Services may receive requests for DCS employees and/or children/youth/families supervised by the department to participate in an external research or evaluation project. Through the research review process, the DCS Research Review Committee (RRC) will decide on the appropriateness of all research requests.

Index 6.1 Effective date: February 1, 2000 CS-0001 Revised date: September 1, 2003

- Any employee or client asked to voluntarily participate in a research project shall be free to participate or decline of his/her own free will.
- Refusing to participate in any research project shall not affect any benefits to which employees or clients or participants are otherwise entitled, and no one shall ever be required to participate in a research study.
- 4. In research studies where applicable laws, standards, regulations, or policy would necessitate the subject's informed consent, those electing to participate shall sign DCS form CS-0334, Requests for Access to Human Subjects or Records Which May Involve Informed Consent, that complies with all provisions established under Title 45 Part 46 of the Code of Federal Regulations.
- 5. This policy shall apply to all research activities or proposals involving use of human subjects or access to confidential records and data (See DCS policy 9.5, Access and Release of Confidential Child-Specific Information), archival research not requiring access to confidential records or human subjects by persons who do not have customary access to such information as part of their job duties, and requests for research data or information not already in the public domain.
- 6. Any proposed research or evaluation project will not interfere with a Department of Children's Services employee from carrying out his/her normal and customary assigned duties, nor shall any proposed project conflict with applicable State Law, Federal Regulations, or American Correctional Association (ACA) standards regarding use of human subjects for research purposes.
- 7. This policy shall not interfere with the Department of Children's Services or a contracted agency from conducting necessary program evaluation studies of existing or proposed programs provided the study does not conflict with applicable State Law, Federal Regulations, or American Correctional Association (ACA) standards regarding use of human subjects for research purposes. When a new external evaluation is planned, the director of Policy, Planning and Research shall be informed and the evaluation plan submitted to the Policy, Planning and Research division for review and approval.
- 8. This policy shall not interfere with the Department of Children's Services from instituting pilot programs used to determine how proposed operational changes will impact

public safety or departmental operations.

 A list of all on-going research or evaluation studies will be maintained in the division of Policy, Planning and Research.

B. Research Review

- Requests for information, data, or statistics which are not already in the public domain, do not involve use of human subjects for research purposes, and do not involve access to any records or files such as departmental or institutional files or records typically not available to the public, shall be submitted on form CS-0541, Requests For Information, and submitted to the Director of Policy, Planning and Research or designee. Approval or disapproval of the request shall include the following factors:
 - a) Applicable state law, federal regulations, and American Correctional Association (ACA) standards;
 - b) The purpose for which the information is to be used and benefits to the department;
 - c) Ability to provide the requested information and
 - d) Cost (time and staff resources) of providing the requested information.
- 2. The Commissioner or Director of Policy, Planning and Research who serves as the Chair of the Committee, shall convene a DCS RRC to include the Assistant Commissioner of Information Management and the appropriate staff relevant to the research subject matter to review all research proposals which involve:
 - a) Access to records, reports, files, or databases by individuals who would not typically have access to this information as part of their customary job duties;
 - b) Access to confidential records (e.g., medical or mental health records) where issues such as informed consent must be considered:
 - Access to use human subjects for research purposes where issues such as informed consent must be considered;
 - All other requests to conduct activities considered to be research from individuals outside the department of children's services or from employees whose job duties

do not typically involve this activity.

- 3. A research request must follow procedures developed by the DCS RRC to obtain all necessary information required to recommend approval or disapproval of research proposals to the Commissioner or his/her designee. If the research involves human subjects or existing records and data with identifying information, the Principal Investigator must complete the appropriate form(s) CS-0334, Requests for Access to Human Subjects or Records Which may Involve Informed Consent or CS-0542, Research Involving Study of Existing Records or Data that are required for the purpose of confidentiality prior to the research activities.
- 4. The information required on the form(s) includes:
 - a) Identifying information about the investigator(s), institutional affiliation, and research credentials;
 - b) Purpose of the research project;
 - c) Proposed research methodology;
 - d) Risks and benefits to the research subjects (if applicable);
 - e) Cost versus benefits to the department;
 - f) Other potential benefits of the research;
 - g) Issues impacting confidentiality of the records or data and preserving anonymity of the research participants;
 - h) Plan for obtaining informed consent (if applicable);
 - Agreement to furnish DCS with research results for review and comment by the appropriate department heads and/or facility administrator prior to publication or dissemination as required by ACA standards.
- 5. The DCS Research Review Committee (RRC):
 - a) May also require independent approval or exemption of the research proposal by an outside Institutional Review Board as defined in the Department of Health and Human Services - Title 45 Part 46, Protection of Human Subjects code of federal regulations and must require IRB review where the CFR regulations require such review (as in research which requires informed consent or presents more than "minimal risk" to participants).

- b) Shall ensure the research proposal complies with all applicable State Law, Federal Regulations, or American Correctional Association (ACA) standards.
- c) Shall disseminate copies or summaries of the research proposal to all assistant commissioners, directors, superintendents, or other agency management whose duties or responsibilities would be affected by the research proposal, for purposes of review and comment.
- d) Shall recommend disapproval of any research proposal disapproved by the affected manager.
- 6. In no case shall the DCS RRC recommend approval of research proposals that violate existing State Law, Federal Regulations, or American Correctional Association (ACA) standards. Specifically prohibited from approval is any research that uses juveniles for medical, pharmaceutical, or cosmetic experiments, or use of medications such as stimulants, tranquilizers, or psychotropic drugs administered for purposes of program management and control or for purposes of experimentation and research.
- 7. Not applicable to this research policy are medications prescribed when clinically indicated as one facet of a program of therapy, or in cases of necessary medical procedures which may not be generally available but are not a part of a general program of medical experimentation.
- 8. The Director of Policy, Planning and Research shall notify the Principal Investigator whether the proposal was approved or disapproved by the committee, and any suggested amendments or changes that would affect this decision and need for resubmission

C. Research Activities

- 1. If approved, the Department shall allow a research project to commence subject to informed consent of the research subjects if applicable.
 - a) The Principal Investigator and all research team members shall be responsible for maintaining confidentiality of the research data and/or subject responses, anonymity of the research participants, conducting themselves within the boundaries of the approved research protocol, and compliance with all applicable State and Federal Laws and Regulations, the American Correctional Association Standards (ACA), and Departmental Policies and Procedures.

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- b) Violation may lead to discontinuance of the current research and/or future research, or subject the violator to civil or criminal penalties.
- c) The Director of Policy, Planning and Research or his/her designee must:
 - Approve any changes to the approved research protocol in writing prior to implementation and the Principal Investigator shall be responsible for obtaining written approval before implementing any changes.
 - Consult the DCS RRC in cases where the proposed change represents a major revision to the research plan, but need not consult the DCS RRC over minor revisions such as wording changes in research instruments, changes in the data coding schema, or other issues that do not represent any increased risk to research participants.
- Upon completion of the research project, the Principal Investigator shall furnish the Director of Policy, Planning and Research or his/her designee a copy of any results, findings, reports, or conclusions prior to publication or dissemination.
- The Director of Policy, Planning and Research or designee Shall submit copies of all research results to the appropriate Assistant Commissioner, Regional Administrator, and facility Superintendent/DCS residential facilities Director for purposes of review and comment.

Forms/Templates

(The forms listed below are not on the server and are exclusive to the division of Policy, Planning and Research.)

CS-0334	Requests for Access to Human Subjects or Records Which May Involve Informed Consent
CS-0541	Requests For Information
CS-0542	Research Involving Study of Existing Records or Data

Collateral Documents

Department of Health and Human Services - Title 45 Part 46 Protection of Human Subjects (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm)

ACA Standards

3-JTS-1F-02

3-JTS-1F-03

3-JTS-1F-04

3-JTS-1F-05

3-JTS-1F-06

3-JTS-4C-45

3-JCRF-1F-05

3-JCRF-1F-06

3-JCRF-1F-07

3-JCRF-1F-08

3-JCRF-1F-09

3-JCRF-4C-26

Glossary

Term	Definition
DCS Research Review Committee (RRC):	A committee comprised of the Director of Policy, Planning and Research (PPR), the Assistant Commissioner of Information Management and staff relevant to the research subject. The Director of PPR serves as the Chair of the Committee.
Institutional Review Board (IRB):	A board established to review research activities in accordance with federal regulations.
Informed Consent:	The voluntary agreement without coercion of any potential research participant after they have received the material facts regarding the nature of the research, and any benefits, risks, consequences, or inconveniences likely to be experienced or

derived from participation.

Principal Investigator: The research director, chief researcher, or project leader who has authority over a research project, typically the individual who applies for research approval to an Institutional Review Board.

Research:

Any interviews, questionnaires which involves the collection of data from files, records, or databases maintained within the department by individuals whose job duties do not customarily require such collection; and/or the testing, observation, interviewing, recording, or manipulation of the behavior of an employee, youth, or other client within the department's scope of service for the purpose of conducting surveys, evaluative

studies, and/or hypothesis testing.